are not banned in the country automatically because of their withdrawal in another country. Reports of withdrawal of drugs in a country are examined after taking into account the adverse event reported, reasons for withdrawal; its usage and strength permitted; its requirement in the country, details of scientific studies and the overall risk benefit ratio of banning the drug. A drug considered harmful or irrational for use in the country by the regulatory authority is prohibited throughout the country for manufacture and sale through a Gazette Notification. Marketing of a prohibited drug is an offence under the Drugs and Cosmetics Act 1940, and the offenders are liable to be prosecuted.

Licensing rules of medicines

1676. SHRI UDAY PRATAP SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what action has been taken by the Drug Controller General of India (DCGI) office to tighten the licensing rules for new medicines; and

(b) the details of existing licensing rules for new medicines?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE) SHRIMATI PANABAKA LAKSHMI): (a) and (b) The rules for licensing of new medicines (New Drugs) prescribed under Rule-122A to E of Drugs and Cosmetics Act and Rules thereunder, were amended *vide* Gazette Notification GSR No. 900(E) dt. 12.12.2001, which streamlined the procedures *viz.* application forms and fee requirements etc. Schedule-Y of Drugs and Cosmetics Rules which provides for requirement of pre-clinical, toxicological and human clinical studies etc. for new drugs has also been recently revised.

These rules are also available at departmental website *www. cdsco. nic. in.*

Further, to restrain State Licensing Authorities from granting of New Drug licenses without approval of competent authority, Rules 69,71,75 & 76 of Drugs & Cosmetics rules were amended *vide* Gazette Notification GSR No. 311 (E), dt. 1.05.2002.